Report

The Analytical Quality of Point-of-Care Testing in the 'QAAMS' Model for Diabetes Management in Australian Aboriginal Medical Services

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Abstract

Type 2 diabetes mellitus and its major complication, renal disease, represent one of the most significant contemporary health problems facing Australia's Indigenous Aboriginal People. The Australian Government-funded Quality Assurance for Aboriginal Medical Services Program (QAAMS) provides a framework by which on-site point-of-care testing (POCT) for haemoglobin A1c (HbA_{1c}) and now urine albumin:creatinine ratio (ACR) can be performed to facilitate better diabetes management in Aboriginal medical services. This paper provides updated evidence for the analytical quality of POCT in the QAAMS Program. The median imprecision for point-of-care (POC) HbA_{1c} and urine ACR quality assurance (QA) testing has continually improved over the past six and half years, stabilising at approximately 3% for both analytes and proving analytically sound in Aboriginal hands. For HbA_{1c}, there was no statistical difference between the imprecision achieved by QAAMS and laboratory users of the Bayer DCA 2000 since the QAAMS program commenced (QAAMS CV 3.6% ± 0.52, laboratory CV 3.4% ± 0.42; p = 0.21, paired t-test). The Western Pacific Island of Tonga recently joined the QAAMS HbA_{1c} Program indicating that the QAAMS model can also be applied internationally in other settings where the prevalence of diabetes is high.

Introduction

Type 2 diabetes mellitus and its major complication, renal disease, represent one of the most significant contemporary health problems facing Australia's Indigenous Aboriginal People.[1-3] The overall prevalence of type 2 diabetes is at least three to four times that of the general population.[1] Hospitalisation rates for diabetes are four times higher for Aboriginal males and six times higher for Aboriginal females compared to non-Aboriginal people. Across Australia, diabetes is responsible for 10.6 times more deaths in Indigenous males and 17.6 times more deaths in Indigenous females than the broader Australian community.[2] Rates of end-stage renal failure (principally as a result of diabetic nephropathy) have risen almost unabated across the past 15 years in many Aboriginal communities.[4-9]

As part of an Australian Government-funded national program called QAAMS which began in 1999, Aboriginal Health Workers from 65 Aboriginal medical services across Australia conduct on-site POCT for HbA_{1c} on the DCA 2000 analyser (Bayer Diagnostics, Tarrytown, NY, USA) to monitor glycaemic control in Aboriginal people with established diabetes.[10-12] Aboriginal health workers are Aboriginal people living and working in the community who have a basic qualification in primary health care. 75% of the participating Aboriginal medical services are located in rural and remote Australia.

In 2003, the QAAMS program expanded to include POC urine ACR testing on the DCA 2000 to further support diabetes management.[13] Urine ACR is a biochemical marker for microalbuminuria or early stages of renal disease which, as mentioned previously, is the major complication of diabetes in Aboriginal people. The initial intake of Aboriginal medical services into the QAAMS urine ACR program was capped by the Australian Government at 30, all of whom were existing sites within the QAAMS HbA_{1c} program. From January 2006, this capping has now been increased to a maximum of 100 Aboriginal medical services for both the urine ACR and HbA_{1c} programs.

The ability to perform both HbA_{1c} and urine ACR tests on-site by POCT provides a powerful and culturally effective platform to improve diabetes management in Australia's

Aboriginal people.[14] However, it is also crucial that analytical performance for conducting POCT in the Aboriginal (non-laboratory) setting meets acceptable analytical performance standards. To measure and maintain the analytical quality of POCT in the QAAMS Program, a broad quality management framework was established. This included a culturally appropriate education and training program with practical and written competency assessment for POCT operators, an internal quality control program and external quality assurance (EQA) testing for HbA_{1c} and urine ACR. This paper provides updated evidence on the analytical quality of POCT in the QAAMS Program, specifically assessed by the results of EQA testing, and also mentions the international applicability of the model.

Methods

The QAAMS Program is a collaborative partnership between the Community Point-of-Care Services Unit within the Flinders University Rural Clinical School and the Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs Pty Ltd, Chemical Pathology Group, Adelaide, Australia. The QA component of the QAAMS HbA_{1c} and urine ACR programs is modelled on the same principles used by the RCPA Quality Assurance Programs in delivering QA programs for laboratories. However selected design elements have been modified to suit the Aboriginal POCT environment, which, for example, does not have access to deionised water or volumetric pipettes for reconstituting quality assurance samples. Each QAAMS participant is thus provided with lyophilised QA samples and either eye droppers (for HbA_{1c}) or sealed plastic tubes (for urine ACR) with a specific volume of deionised water for making up the samples. Two samples per month are tested across two six-monthly testing cycles per year. The samples for each cycle comprise paired and linearly-related levels of analyte across a range of concentrations from 5 to 14% for HbA_{1c} and 1 to 25 mg/mmol for urine ACR. The use of paired samples enables calculation of imprecision for QA testing on the DCA 2000 for both individual services and the group as a whole.

Services receive a monthly summary report shortly after the end of each month. The report format, which has been published previously, summarises both short and long term analytical performance.[10,13] Each site has its own Community Number to ensure confidentiality of results. At the end of each month, the QA results from all participating services are reviewed. If the QA results returned by a particular service are outside the limits of acceptability established by the program organisers ($\pm$ 0.5 up to an HbA_{1c} of 10% and $\pm$ 5% at HbA_{1c} >10%, and $\pm$ 15% for urine ACR), the service's previous results are assessed for trends over recent months, the service is contacted and the possible reasons for the poor performance are discussed with the POCT operator. Poorly performed services are monitored closely until their performance improves. The QAAMS Program also has a telephone support service (attended during normal business hours). Using this service, POCT operators can contact a member of the QAAMS management team to discuss any technical or analytical issue as it arises.

At the completion of each six-monthly cycle, key performance indicators are calculated including:

- Participation Rate (number of QA results returned as a % of the maximum number of results that could be returned).
- % Acceptable Results (the % of results within preset limits of acceptability set by the QAAMS management team, as stated previously).
- Median within-site imprecision (CV%), calculated by dividing the standard deviation of the midpoint of the service's range of concentrations, expressed as a percentage. Imprecision is considered a crucial performance indicator because serial POCT HbA_{1c} and urine ACR measurements are conducted for patient management in the QAAMS program. It is important that analytical noise is minimised and does not mask clinically significant changes in patient results across time. Current guidelines for Aboriginal and Torres Strait Islander Peoples recommend that HbA_{1c} is conducted every three months, while urine ACR is performed annually if the patient has a normal ACR and six monthly if the patient has microalbuminuria.[15]
- Median within-site bias, which is the average of biases of the service's line of best fit at the lowest, highest and midpoint concentrations, irrespective of sign. For HbA_{1c} samples, a target value was assigned to each sample using an international primary reference method for HbA_{1c} (DCCT Biorex 70 HPLC).[16] For urine ACR samples, the median of all results submitted for each sample was used as the target because no international primary reference measurement systems are currently available.

Results

For HbA_{1c} QA testing, the participation rate across 13 six-monthly testing cycles from July 1999 to December 2005 has averaged 86% (range 73 to 89%). Eighty five percent of 6148 QA results submitted over these 13 testing cycles were within the preset limits of acceptability. The median within-site imprecision (CV%) achieved by services has consistently improved over the six and a half years since the program began (Figure 1), averaging 3.6% across the lifetime of the program and 3.2% across the past three years. Within-site

accuracy has remained steady, with the median bias averaging 0.22% (range 0.17 to 0.38%) across the 13 testing cycles.

It is possible to directly compare the performance of QAAMS Aboriginal medical services with laboratory users of the DCA 2000 (of which there are approximately 70) because the QAAMS and the laboratory-based RCPA Glycohaemoglobin QAP use the same material. The performance achieved for QA testing by Aboriginal medical services and laboratories using the DCA 2000 across the past six and a half years are shown in the Table. The median CV% for laboratory users of the DCA 2000 has averaged 3.4% since 1999 and 3.2% across the past three years. There was no statistical difference between the median CV% achieved by QAAMS and laboratory users of the DCA 2000 since the QAAMS program commenced (QAAMS 3.6% ± 0.52, laboratory 3.4% ± 0.42; t = 1.96, df = 12, p = 0.21, paired t-test).

For urine ACR QA testing, the participation rate across six 6-monthly testing cycles from January 2003 to December 2005 has averaged 85% (range 74 to 91%). Ninety six percent of 1754 QA results submitted over these six testing cycles were within the preset limits of acceptability. The median imprecision (CV%) achieved by services for urine ACR testing has consistently improved over the three years since the program began (Figure 2), averaging 4.4% across the lifetime of the program and 2.9% over the past two years. Within-site accuracy has remained steady, with the median bias averaging 0.42% (range 0.28 to 0.62%) across the six testing cycles.

Discussion

The results presented in this paper confirm that the QAAMS model for POCT HbA_{1c} and urine ACR testing provides a health service delivery system that is analytically sound in Aboriginal hands. The imprecision achieved for HbA_{1c} QA testing by Aboriginal health workers has continually improved across the duration of the QAAMS Program and was statistically equivalent to that achieved by trained laboratory scientists and technicians using the DCA 2000 point-of-care analyser.

Precision goals for HbA_{1c} methods have continually been refined downwards over the past decade as the clinical requirement for tight imprecision has been highlighted through the results of international studies such as the Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study.[17,18] The minimum precision goal for POC HbA_{1c} testing recommended by the Australian Government Department of Health and Ageing's Interim Standards for Point-of-Care Testing in General Practice is 4% and represents a consensus of published information.[19] Many professional bodies have recommended a desired precision goal of 3% for laboratory HbA_{1c} methods, as this degree of precision can statistically distinguish between recommended HbA_{1c} treatment goals of 7% and 8%.[20-22] A recent international workshop advocated the optimal precision goal for laboratory HbA_{1c} methods should be 2% because this level of precision 'justifies clinicians acting on differences of 0.35% to 0.5% as being significant'.[23,24] As can be seen in Figure 1, QAAMS participants achieved a precision base which was just outside the minimum goal in the first year of the program. Over the next three and a half years, services achieved a precision base

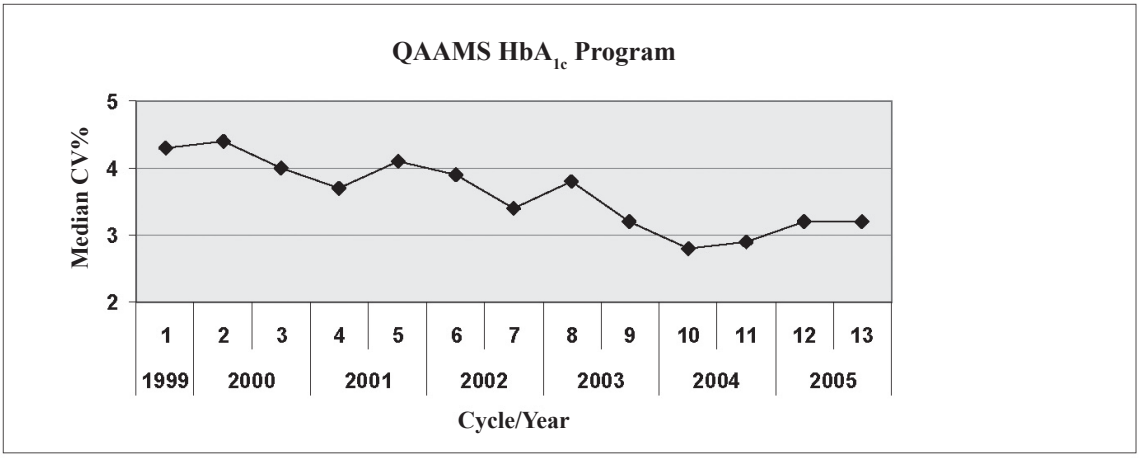

Figure 1. Median Precision Achieved by Aboriginal Medical Services in the QAAMS Program for POC HbA1c testing from 1999-2005.

Table. Comparative precision base (median CV%) over the last equivalent 13 testing cycles: Aboriginal Medical Services (AMS) versus laboratories using the Bayer DCA 2000.

Program	Year	1999	2000		2001		2002		2003		2004		2005	
	Cycle	1	2	3	4	5	6	7	8	9	10	11	12	13
	Type of Service													
QAAMS	AMS	4.3	4.4	4.0	3.7	4.1	3.9	3.4	3.8	3.2	2.8	2.9	3.2	3.2
Glycohaemoglobin	Labs	4.1	3.0	3.0	3.4	4.1	3.7	3.5	3.6	3.3	3.1	3.2	2.7	3.1

that was well within the minimum goal. In 2004, they achieved better than the desired goal of 3%. Over the past year, median performance for HbA_{1c} QA testing in the QAAMS program has stabilised at around the 3% mark, potentially reaching the maximum analytical capability of the DCA 2000 POCT analyser.

The minimum precision goal for POC urine ACR testing recommended by the Australian Government's Department of Health and Ageing's Interim Standards for Point-of-Care Testing in General Practice is 12%, with this goal also representing a consensus of published information.[19,21] As seen from Figure 2, this goal has also been readily achieved by Aboriginal medical services in the QAAMS program.

The analytical performance recorded by QAAMS participants for these two tests represents an outstanding achievement, acknowledging that POCT in the QAAMS program is being undertaken by non-laboratory trained health workers from services scattered across Australia with many services enduring difficult working conditions, particularly in remote Australia, and high rates of staff turnover. It reflects an on-going commitment not only by the QAAMS management team to continuing education, training and competency assessment but also by the dedicated teams of Aboriginal health workers conducting POCT in their services. Whilst this paper has focused specifically on observed improvements in analytical quality, it should be noted that the QAAMS program has also been shown to be both culturally appropriate and clinically effective in improving glycaemic control in Aboriginal hands.[14] In the long term, the QAAMS program aims to collect data on the impact of the program on reduction of morbidity and mortality.

The successful adaptation of the QAAMS model for urine ACR testing in 2003 demonstrates that the model is transferable to other POC tests. The Diabetes Centre from the Western Pacific island of Tonga recently joined the QAAMS

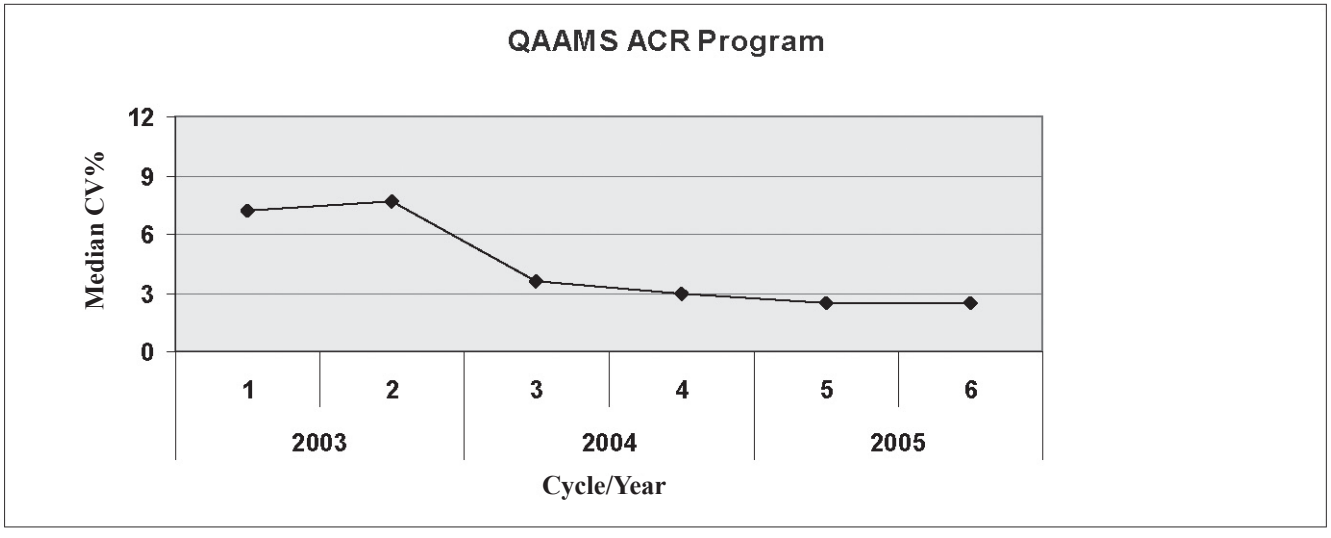

Figure 2. Median Precision Achieved by Aboriginal Medical Services in the QAAMS Program for urine ACR testing from 2003-2005.

network, with the approval of the Australian Government. The QAAMS Program Manager trained a team of health workers from Tonga at the Australian Centre for Diabetes Strategies. A high prevalence of diabetes (15%) has been reported in Tonga, where the disease causes similar problems to those faced by Aboriginal Australians.[25] The Bayer DCA 2000 offered a practical option for the Diabetes Centre to provide better care and monitoring for many of its diabetes patients. The results of recent QA testing in Tonga indicates that sound analytical performance for POCT HbA_{1c} testing can also be obtained in Indigenous health services outside Australia that have access to the same education, training and QA testing framework provided by QAAMS. This finding also confirms the transferability of the QAAMS model to other health settings and illustrates the potential of this POCT model to be expanded internationally to support diabetes management in other countries where the burden of diabetes is similarly high or where health services have limited access to laboratory services due to geographic isolation.

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References

1. Couzos S, O'Rourke S, Metcalf S, Murray R. Diabetes. In: Couzos S, Murray R, editors. Aboriginal primary health care. An evidence-based approach. 2nd ed South Melbourne, Victoria: Oxford University Press; 2003. p. 348-410.
2. Australian Bureau of Statistics, Australian Institute of Health and Welfare. The health and welfare of Australia's Aboriginal and Torres Strait Islander people 2005. Canberra: Australian Institute of Health and Welfare and the Australian Bureau of Statistics; 2005.
3. International Diabetes Institute. Review of the epidemiology, aetiology, pathogenesis and preventability of diabetes in Aboriginal and Torres Strait Islander populations. Canberra, Australian Capital Territory: Office for Aboriginal and Torres Strait Islander Health Services, Commonwealth Department of Health and Family Services; 1998.
4. Thomas MA. Kidney disease in Australian Aboriginals: time for decisive action. Med J Aust 1998;168: 532-3.
5. Spencer JL, Silva DT, Snelling P, Hoy WE. An epidemic of renal failure among Australian Aboriginals. Med J Aust 1998;168:537-41.
6. Hoy W, Van Buynder P, Mathews JD, Puglsey DJ, Wang Z. Renal disease and the environment: lessons from Aboriginal Australia. Nephrol 2001;6:19-24.
7. Hoy WE, Baker PR, Kelly AM, Wang Z. Reducing premature death and renal failure in Australian Aboriginals. A community-based cardiovascular and renal protective program. Med J Aust 2000;172:473-8.
8. Hoy WE. Renal disease in Australian Aboriginals. Med J Aust 1996;165:126-7.
9. Couzos S, Thomas M. Chronic renal failure. In: Couzos S, Murray R, editors. Aboriginal primary health care. An evidence-based approach. 2nd ed South Melbourne, Victoria: Oxford University Press, 2003; p. 424-60.
10. Shephard MD, Gill J. Results of an innovative education, training and quality assurance program for point-of-care HbA_{1c} testing using the Bayer DCA 2000 in Australian Aboriginal Community Controlled Health Services. Clin Biochem Rev 2003;24:123-30.
11. Shephard MD. Point-of-care testing in the indigenous rural environment – the Australasian experience. In: Price C, Hicks J, St John A, editors. Point-of-Care Testing. Washington DC: AACC Press; 2004. p. 293-301.
12. Shephard MD, Mundraby K. Assisting diabetes management through point-of-care HbA_{1c} testing – the 'QAAMS' program for Aboriginal health workers. Aborig Isl Health Worker J 2003;27:12-8.
13. Shephard MD, Gill JP. An innovative Australian point-of-care model for urine albumin:creatinine ratio testing that supports diabetes management in indigenous medical services and has international application. Ann Clin Biochem 2005;42:208-15.
14. Shephard MD. Cultural and clinical effectiveness of the 'QAAMS' point-of-care testing model for diabetes management in Australian Aboriginal medical services. Clin Biochem Rev 2006;27:161-70.
15. Couzos S, Metcalf S, Murray R, O'Rourke S. Systematic review of existing evidence and primary care guidelines on the management of non-insulin-dependent diabetes in Aboriginal and Torres Strait Islander populations. Canberra, Australian Capital Territory: Office for Aboriginal and Torres Strait Islander Health, Commonwealth Department of Health and Aged Care; 1997.

16. Goldstein DE, Little RR, England JD, Wiedmeyer HM, McKenzie EM. Methods for quantitating glycosylated haemoglobins: high performance liquid chromatography and thiobarbituric acid colorimetry. In: Clarke WL, Larner J, Pohls SL editors. Methods in diabetes research, Vol 2: Clinical methods. New York: John Wiley; 1986. p. 475-504.
17. Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-86.
18. UK Prospective Diabetes Study (UKPDS) Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-53.
19. Shephard MD. Analytical performance criteria for point-of-care testing instruments. Part 10. In: Standards for Point of Care Testing in general practice. Incorporating POCT Trial Guidelines. Canberra, Australian Capital Territory: Australian Government Department of Health and Ageing; 2004. p. 110-140.
20. Coleman PG, Goodall GI, Garcia Webb P, Williams PF, Dunlop ME: Glycohaemoglobin: a crucial measurement in modern diabetes management. Progress towards standardisation and improved precision of measurement. Med J Aust 1997;167:95-8.
21. Sacks DB, Bruns DE, Goldstein DE, MacLaren NK, McDonald JM, Parrott M. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 2002;48:436-72.
22. White GH, Farrance I. Uncertainty of measurement in quantitative medical testing – a laboratory implementation guide. Clin Biochem Rev 2004;25 (Suppl): S1-S24.
23. Goodall I. HbA_{1c} standardisation destination – Global IFCC standardisation how, why, where and when. Clin Biochem Revs 2005;26:5-19.
24. Boulton AJ, Saudek CD. The need for standardisation of glycated haemoglobin measurements. Diabetologia 2002;45:R19-21.
25. Colagiuri S, Colaguiri R, Na'ati S, Muimuiheata S, Hussain Z, Palu T. The prevalence of diabetes in the Kingdom of Tonga. Diabetes Care 2002;25;1378-83.

Erratum:

In the 2005 May;26(ii)issue of the Journal, page 16 (Appendix) of the article "The Evidence Based Medicine Approach to Diagnostic Testing: practicalities and limitations" the reference for Search Findings: should be Kuhlman KA, Hennessey WJ. Sensitivity and specificity of carpal tunnel syndrome signs. American Journal of Physical Medicine & Rehabilitation 1997;76(6):451-7.